510(k) Summary

MAR 1 2 2013

Submitter:	Philips Medical Systems 3000 Minuteman Road Andover MA, 01810 USA
Contact Person:	Mark Puopolo Sr. Manager, Regulatory Affairs Phone: 978.659.4244 Fax: 978.659.3690 mark.puopolo@philips.com
Date Prepared:	January 15, 2013
Trade Name:	HeartStart MRx with Airway Confirmation Assist Defibrillator/Monitor
Common Name:	Automatic External Defibrillator
Classification Name:	Automatic External Defibrillator
Predicate Device:	Philips HeartStart MRx Defibrillator/Monitor (K061707) Oridion Capnostream 20 (K082268) Zoll E Series Defibrillator/Monitor with Intubation Assist Option (K080903)
Device Description:	The Philips HeartStart MRx with Airway Confirmation Assist (ACA) Defibrillator/Monitor is a modification of the FDA cleared HeartStart MRx Defibrillator/Monitor. This function of the MRx used to verify airway placement and aid in assessing ventilatory status when an adult or pediatric patient is being ventilated using an endotracheal or supraglottic airway and the airway is being monitored using capnography. Based on predetermined criteria, Airway Confirmation Assist continuously analyzes the CO_2 waveform coming from the capnography monitor to decide if the waveform represents a valid breath. If the Airway Confirmation Assist is enabled in the MRx, and based on characteristics of the valid breaths, ACA will decide if the airway is established. It will then report a Pass/Fail decision to the MRx. The defibrillator/monitor will display the result to the user in the configured format (graphic and text). As an adjunct to clinical

examination, ACA provides additional information along with capnography to help in verifying airway placement and aiding in assessment of ventilation status.

Statement of Intended Use:

The HeartStart MRx is intended for use in the hospital and pre-hospital settings by qualified medical personnel trained in the operation of the device and qualified by training in basic life support, advanced life support, advanced cardiac life support or defibrillation.

When operating as a semi-automatic external defibrillator in AED Mode, the HeartStart MRx is suitable for use by medical personnel trained in basic life support that includes the use of an AED.

When operating in Monitor, Manual Defib or Pacer Mode, the HeartStart MRx is suitable for use by healthcare professionals trained in advanced cardiac life support.

The SMART Biphasic waveform utilized in the HeartStart MRx has previously undergone clinical testing in adults. These trials support the waveform's effectiveness for defibrillation of ventricular tachyarrhythmias at 150J.

Summary of Technological Characteristics:

In addition to being technologically equivalent to the predicate devices, the HeartStart MRx with Airway Confirmation Assist Defibrillator/Monitor has been subjected to performance and usability testing and it has been determined that the HeartStart MRx with Advanced Airway Confirmation Defibrillator/Monitor is suitable for its intended use.

Summary of Non-clinical Data:

HeartStart MRx with Airway Confirmation Assist Defibrillator/Monitor is manufactured under the same conditions, using the similar processes and identical materials, as the Philips HeartStart MRx Defibrillator/Monitor, the legally marketed Philips Medical Systems predicate device. In addition to being technologically equivalent, the indications for use have not changed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 12, 2013

Mr. Mark Puopolo
Sr. Manager, Regulatory Affairs
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810

Re: K130153
HeartStartMRx Defibrillator/Monitor
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulation Class: Class III
Product Code: MKJ (LDD, DRO, DPS, DXN, CCK, DQA, MWI, LIX)
Dated: January 23, 2013
Received: January 24, 2013

Dear Mr. Mark Puopolo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K130153

Device Name: The HearStart MRx with Advanced Airway Confirmation Defibrillator/Monitor

Indications for Use: The HeartStart MRx is for use for the termination of ventricular tachycardia and ventricular fibrillation.

The device is for use by qualified medical personnel trained in the operation of the device and qualified by training in basic life support, advanced cardiac support, or defibrillation. It must be used by or on the order of a physician.

AED Therapy: To be used in the presence of a suspected cardiac arrest on patients of at least 8 years of age that are unresponsive, not breathing and pulseless.

Manual Defibrillation: Asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients that are pulseless and unresponsive. Synchronous defibrillation is indicated for the termination of certain atrial and ventricular arrhythmias.

Noninvasive External Pacing Therapy: The pacing option is intended for treating patients with symptomatic bradycardia. It can also be helpful in patients with asystole, if performed early.

Pulse Oximetry: The SpO2 option is intended for use when it is beneficial to assess the patient's oxygen saturation level.

Noninvasive Blood Pressure Monitoring: The NBP option is intended for noninvasive measurement of a patient's arterial blood pressure.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Number (if known): K130153

Device Name: The HearStart MRx with Advanced Airway Confirmation Defibrillator/Monitor

Indications for Use: [continued...]

End-Tidal CO2: The EtCO2 option is intended for noninvasive monitoring of a patient's exhaled carbon dioxide and to provide a respiration rate.

12-Lead ECG: The 12-Lead ECG function is to provide a conventional diagnostic 12-Lead-ECG report, which may include measurement and interpretative statements.

Q-CPR: The Q-CPR option provides feedback designed to encourage rescuers to perform resuscitation in accordance with AHA/ERC guidelines for chest compression rate depth, and duty cycle and ventilation rate, volume and flow rate (inflation time).

Invasive Pressures: The Invasive Pressures option is indicated for measuring arterial, venous, intracranial, and other physiological pressures on patients.

Temperature: The Temperature option is indicated for measure temperature in patients.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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